Unit 6, No. 131, 3rd floor,
Shokrollah St. (1st), North
Kargar St, Tehran, Iran
Postal Code: 1413684892

Tel: +98 (21) 88354257

www.AryaMedTech.com
Info@aryamedtech.com

Nano
HesgarSazan
Salamat Arya

CDP

Cancer Diagnostic Probe

with Margin and Mass Modes

Product Introduction

The main goal of Breast-Conserving Surgery (BCS) is to remove cancer tumors with safe margins intraoperatively to prevent the second surgery. Remaining positive margins in breast-conserving surgery are associated with an increased risk of local recurrence, leading to healthcare costs and mental and physical stress. Direct checking of cavity side margins after tumor excision may prevent the tumor bed from remaining tumor residues/satellite/scattered cancer cells. Published reports indicated that more than 20% of the involved margins, still could not be diagnosed intraoperatively by conventional intraoperative methods such as frozen section and X-ray evaluation of dissected tumor margins.

Cancer Diagnostic Probe (CDP), a real-time diagnostic system as a complementary surgeon-assisted tool, along with Frozen-section and Permanent pathologies, is used to detect high-risk pre-cancer/cancer cells in the cavity side margins of patients undergoing breast cancer surgery.

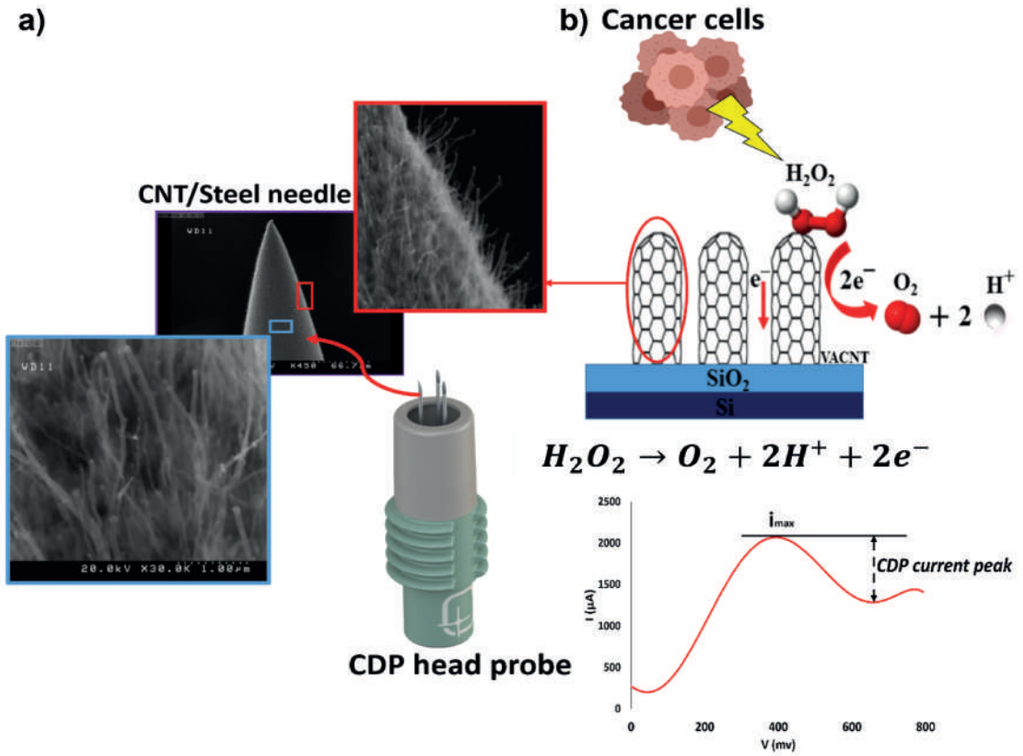
CDP

Cancer Diagnostic Probe

with Margin and Mass Modes

CDP in the margin mode

CDP's detection mechanism in the margin mode has been based on real-time detection of released ROS/H_2O_2 molecules by cancer cells during tumor initiation, reverse Warburg effect, and hypoxia-assisted glycolysis.



a) Image of the CDP Margin HeadProbe in the margin mode, consisting of three needle electrodes coated by multi-wall carbon nanotubes (MWCNTs).

b) Selective electrochemical reactions of released ROS/H_2O_2 on MWCNTs and production of the electrochemical cathodic peak.

Statistical diagnostic results of CDP in the margin mode

* Percentage reduction of the involved margins remaining in the patient's body with the help of CDP despite performing Frozen-section and Permanent pathology on tumor side margins (%)

Diagnostic results	Margin mode	
	Non-Neoadjuvant	Neoadjuvant
Number of patients	395	105
Number of samples	5005	1495
Sensitivity (٪)	93	90
Specificity (٪)	91	89
CDP effectiveness (٪) *	35%	33%

Features

- Real-time and non-invasive detection of involved cavity side margins with precancerous/cancerous cells, which are not detected by frozen-section pathology, with a diagnostic accuracy of over 93% during breast cancer surgery.
- Reduction of about 30% of the involved margins remaining in the patient’s body with the help of CDP despite performing frozen-section and permanent pathology on tumor side margins.
- Intraoperative diagnosis of excision-required newly discovered solid masses that were not evaluated in presurgical evaluations.
- Increasing the prognosis factor and reducing the local recurrence rate in breast cancer patients.
- Using disposable head probes to prevent the transmission of contamination.

Standards

- IEC 60601-1: 2016: international Standard: General requirements for basic safety and essential performance for medical equipment.
- IEC 60601-1-2: 2014: EMC Compliance, General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- ISO 62304: Medical Device software - Life cycle Process.
- ISO 10993-10: Biological evaluation of medical devices: Part 10: test for irritation and skin sensitization.
- ISO 10993-5: Biological evaluation of medical devices: Part 5: test for in-vitro cytotoxicity.
- ISO 11607-1: Packaging for terminally sterilized medical devices PART1: requirement for materials, sterile barrier systems, and packaging systems.
- INSO 3001-1: Sterility compliance.
- ISO 13485: Medical Devices - Quality management systems.

Articles & Patents

This device has a license issued by the Food and Drug Administration (General Department of Medical Equipment) of the Health Ministry of the Islamic Republic of Iran No. 23212882. It also has 5 ISI-published papers and 5 granted USA patents.

Margin and mass modes:

- Bioengineering and translational medicine
- International Journal of Medical Robotics and Computer Assisted Surgery
- Cancer medicine
- Journal of Cancer Research and Clinical Oncology
- Biosensors and Bioelectronics

Granted USA Patents:

- US 11,179,076 B2
- US 10,786,188 B1
- US 11,179,077 B2
- US 11,181,499 B2
- US 11,806,140 B2

CDP Scoring In the Margin mode Based on WHO Classification of Breast Tumor Disease